Official Utah Department of Health Alert and Update
COVID-19 Response – Persons Under Investigation Update
HAN #: 04032020-01

Title: Updated criteria for laboratory testing at the Utah Public Health Laboratory (UPHL) for COVID-19

Summary/Background:
The Utah Department of Health (UDOH) is constantly monitoring laboratory testing availability. During testing resource limitations, UDOH will limit testing at the UPHL to patients who meet the below criteria. Testing resource limitations will be noted on the UDOH COVID-19 website (coronavirus.utah.gov). UDOH will prioritize testing those who rely upon the public health system for COVID-19 testing (e.g., uninsured, jails/prisons, homeless, etc.).

Depending on availability, providers have the option to order testing from clinical laboratories, both in Utah and nationwide, as an alternative to using UPHL. Individual healthcare systems might have their own testing protocols.

To request testing from UPHL, please visit: UDOH COVID-19 Test Request Tool, which is also available at coronavirus.utah.gov. UDOH is relying on clinicians to be good stewards of our limited testing resources by following the below guidance.

Testing should be provided to all patients with fever **or** signs/symptoms of lower respiratory illness (e.g., cough or shortness of breath) AND any of the below epidemiologic risk factors. When testing resources are limited, testing will be prioritized according to the below rank order of epidemiologic risk factors.

Testing will be provided to patients with fever or signs/symptoms of lower respiratory illness (e.g., cough or shortness of breath) AND:

Epidemiologic Risk Factors
PRIORITY 1: • Hospitalized patients (to inform infection control) • Healthcare personnel and first responders providing direct patient care • Any person who lives or works in a congregate setting such as a nursing home, correctional facility, or shelter • Individuals who may have other illnesses that would be treated differently if they were infected with COVID-19
PRIORITY 2: Any person who has had close contact with a laboratory- confirmed COVID-19 patient within 14 days of symptom onset[1] **AND** the patient meets one of the CDC's defined high-risk criteria[2]
PRIOIRTY 3: Any person who has had close contact with a laboratory- confirmed COVID-19 patient within 14 days of symptom onset[1] **OR** the patient meets one of the CDC's defined high-risk criteria[2]
PRIORITY 4: No source of exposure has been identified

[1] When testing resources are limited, household contacts with fever or signs/symptoms of lower respiratory infection (cough or shortness of breath) do not need to be tested unless admitted to a healthcare facility. All household contacts should self-isolate in their homes for 14 days following symptom onset of the last symptomatic member of the household.

People with clinically diagnosed or laboratory confirmed COVID-19, but who have recovered, can be released from isolation 7 days after symptom onset AND at least 3 days after symptom resolution, according to CDC guidance. All asymptomatic household contacts should self-quarantine in their homes for 14 days following symptom onset of the last symptomatic member of the household.

[2] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/groups-at-higher-risk.html

Testing of asymptomatic persons is not a priority. When testing resources are limited, testing will be prioritized to **priority 1** in the table above. When testing capacity of COVID-19 is limited, please do not submit testing requests for people outside of priority 1. If you submit a test request for someone who does not meet the criteria outlined in priority 1 above, the sample will not be tested. The Test Request Tool will indicate if testing is limited to priority 1.

If you have a patient that meets the above criteria:

- Collect NP swab into a single vial of Viral Transport Media and submit according to the attached guidance.
- OP swabs are no longer recommended.
- Alternative swabs and transport media approved when NP swabs are limited. Please check with the submitting laboratory to determine if these alternatives are acceptable.
- Visit the UDOH COVID-19 Test Request Tool, fill out the online survey and get testing approval.
- Complete a UPHL request form to submit with the specimen. The form is attached or can be downloaded as a fillable PDF at uphl.utah.gov.

This guidance is intended to clarify who may be tested based on clinical or epidemiologic criteria at the Utah Public Health Laboratory. It is NOT meant to be a directive as to whom must be tested.

At this time, healthcare providers caring for patients with fever and severe lower respiratory illness without any epidemiologic risk for COVID-19 should use contact and droplet precautions with eye protection (unless another diagnosis requires a higher level of precaution, e.g., tuberculosis).

Recommendations

- All patients in the healthcare setting who are being assessed for COVID-19 should be isolated in a private room with limited traffic and a closed door. The patient should wear a surgical mask when someone else enters the room.
- Patients who are being tested for COVID-19, but do not require hospitalization, should adhere to home isolation until testing is completed.
- Healthcare personnel caring for patients with fever and severe lower respiratory illness WITHOUT any epidemiologic risk for COVID-19 should:
  - use standard, contact, and droplet precautions with eye protection;
  - proceed to work-up for common causes of respiratory illness (e.g., FilmArray);
  - if no alternative explanatory diagnosis, consider an infectious disease consultation.
- NP swabs can be collected concurrently as other samples being collected for infectious disease rule out (e.g., influenza and respiratory FilmArray or similar broad panel).
- If a patient is being considered for COVID-19, use standard, contact, and droplet precautions with eye protection when providing care. Respirators should be reserved for aerosol-generating procedures.
- Healthcare personnel that cared for a suspect or a confirmed COVID-19 case should have their exposure risk assessed and be excluded from work based on the CDC's work restriction recommendations.

For more information:

- UDOH COVID-19 Information: coronavirus.utah.gov
- CDC information for healthcare professionals: cdc.gov/coronavirus/2019-ncov/hcp/index.html
- CDC guidance for home isolation: cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html
- CDC guidance for healthcare personnel exposure assessment and work restriction recommendations: cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

Contact: For questions, please call 1-888-EPI-UTAH (374-8824).

Utah Public Health Laboratory

Interim Guidelines for Clinical Specimens from Patients Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)

All testing for COVID-19 should be conducted in consultation with a healthcare provider, and only for patients demonstrating symptomatic disease. Samples are received at UPHL, M-F 0800-1700 and Saturday/Sunday 0800-1600. Standard Precautions should be taken in collecting and handling specimens that may contain SARS COV2 virus. Timely communication between clinical, laboratory, and UDOH/Local Health Department staff is essential to minimize the risk incurred in handling specimens from patients with possible COVID-19 infection. General and specific biosafety and submission guidelines for handling, processing, and shipping COVID-19 specimens are provided.

General Guidelines for COVID-19

For initial diagnostic testing for SARS COV2 virus, CDC recommends collecting and testing **a single upper respiratory specimen (NP – nasopharyngeal swab) collected and received in appropriate transport media.** When collection of a nasopharyngeal swab is not possible, the following are acceptable alternatives:

- An oropharyngeal (OP) specimen collected by a healthcare professional, or
- A nasal mid-turbinate (NMT) swab collected by a healthcare professional or by onsite self-collection (using a flocked tapered swab), or
- An anterior nares specimen collected by a healthcare professional or by onsite self-collection (using a round foam swab).

For NP, a single polyester swab with a plastic shaft should be used to sample both nares. NP or NMT swabs should be placed in a transport tube containing either viral transport medium, Amies transport medium, or sterile saline.

If both NP and OP swabs both are collected, they should be combined in a single tube to maximize test sensitivity and limit testing resources.

CDC also recommends testing lower respiratory tract specimens, if available. For patients who develop a productive cough, sputum should be collected and tested for SARS-CoV-2. The induction of sputum is not recommended. When it is clinically indicated (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage

sample should be collected and tested as a lower respiratory tract specimen. **In general CDC is now recommending collecting only the NP swab.**

Specimens should be collected as soon as possible once a decision has been made to pursue COVID-19 testing, regardless of the time of symptom onset.

Store specimens at 2-8°C and ship to Utah Public Health Laboratory (UPHL) on ice packs. Label each specimen container with at least two unique identifiers. Frozen specimens should be shipped on dry ice with appropriate shipping protocols. Questions regarding laboratory response, specimen submission, or testing guidance can be directed to the UPHL Coronavirus response team at 385-258-6249 (24/7). The CDC's diagnostic test has been authorized by FDA under the Emergency Use Authorization (EUA). Utah Public Health Laboratory is performing the EUA RT-PCR assay.

Respiratory Specimens

A. Lower respiratory tract

1. Broncho alveolar lavage (BAL), tracheal aspirate

   Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship to UPHL on ice pack.

2. Sputum

   Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen (sterile, leak-proof, screw-cap sputum collection cup or sterile dry container) at 2-8°C and ship to UPHL on ice pack.

B. Upper respiratory tract: Nasopharyngeal swab AND oropharyngeal swab (NP/OP swab)

Use only synthetic fiber swabs with plastic shafts in sterile tubes containing 2-3 ml of **viral transport media.** NP and OP specimens can be kept in separate vials, or submitted in a single transport tube. Refrigerate specimen(s) at 2-8°C and ship to UPHL on ice pack.

Nasopharyngeal swab: Insert a swab into nostril parallel to the palate. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.

Oropharyngeal swab (e.g., throat swab): Swab the posterior pharynx, avoiding the tongue.

C. Nasopharyngeal wash/aspirate or nasal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship to UPHL on ice pack.

NOTE: Testing for other respiratory pathogens should be done as part of the initial evaluation by the provider. If a PUI tests positive for another respiratory pathogen, after clinical evaluation and consultation with public health authorities, they may no longer be considered a PUI.

STORAGE

Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.

NOTES ON COLLECTION

- Storage: 4-8 C, -70 if >72hr.
- Package as Category B (like most send-outs).
- Ship on wet ice/cold pack.
- Every specimen must have a Utah Public Health Laboratory requisition. PLEASE PRINT CLEARLY AND FILL OUT AS COMPLETELY AS POSSIBLE. Use the Infectious Disease Request Form (https://uphl.utah.gov/wp-content/uploads/UPHL_TEST_REQUEST_FILLABLE.pdf) Requisitions must include:
    - Provider Code
    - Specimen source (please indicate if swabs are combined in a single tube)
    - Test name. Indicate “COVID-19” as Other Disease Suspected (lower left box)

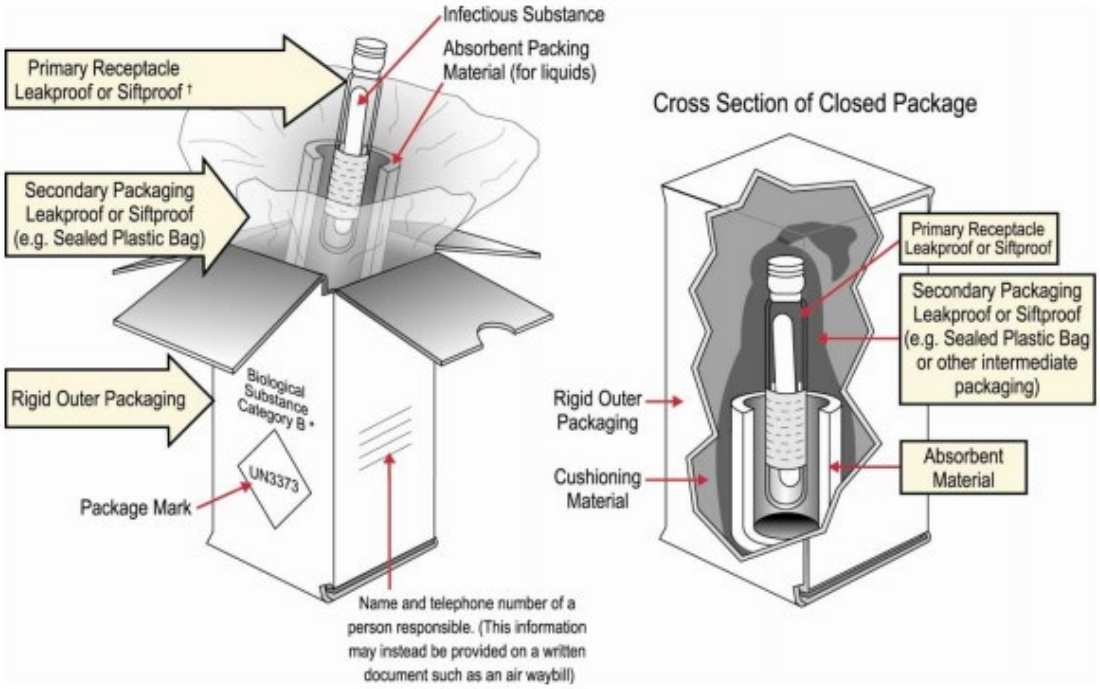
Packing, Shipping and Transport

Specimens transported by motor vehicle fall under DOT regulations, which allows packaging exceptions for some Biological substances, category B. Many hospital labs offer specimen courier service for other infectious tests. **Specimens in biohazard bags, which those couriers then place in closed containers in their vehicle for transport to a reference lab for testing are acceptable for UPHL.**

If you follow DOT regulations, patient specimens (not category A) are not regulated as infectious substances when transported by an "exclusive use courier." This means the shipper decides how to package it by following OSHA regulations, in-house protocols, and safe practices considering both the safety of the courier and personnel in the receiving lab, and protocols that ensure specimen integrity when using an exclusive courier.

Packaging, shipping, and transport of specimens from suspect cases or COVID-19 PUI's must follow the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations for shipment by air transport. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential COVID-19 specimens by transport other than "exclusive use courier".

UN 3373 Category B schematic for packaging



General Biosafety Guidelines (for working with potentially infectious materials)

Clinical laboratories performing routine hematology, urinalysis, and clinical chemistry studies, and microbiology laboratories performing diagnostic tests on serum, blood, or urine specimens should follow standard laboratory practices, including Standard Precautions, when handling potential 2019-nCoV specimens. Appropriate physical containment devices (e.g., centrifuge safety buckets; sealed rotors) should be used for centrifugation. Ideally, rotors and buckets should be loaded and unloaded in a BSC.

Testing of PUI specimens that involve any procedure with the potential to generate fine-particulate aerosols or droplets (e.g., vortexing) should be performed in a Class II Biological Safety Cabinet (BSC). In the case of lack of access to a BSC, or any procedures outside of a BSC eye and face protection (e.g. goggles, mask, and face shield) or other physical barriers (e.g. splash shield) should be used to minimize the risk of exposure to laboratory staff.

After specimens are processed, decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against other respiratory pathogens, such as seasonal influenza and other human coronaviruses. Follow manufacturer's recommendations for use – dilution (i.e., concentration), contact time, and care in handling.

For COVID-19 laboratory waste, follow standard procedures associated with other respiratory pathogens, such as seasonal influenza and other human coronaviruses.

Specific Biosafety Guidelines

The following activities may be performed in BSL-2 facilities using standard BSL-2 work practices:

- Routine examination of bacterial and mycotic cultures
- Routine staining and microscopic analysis of **fixed** smears
- Final packaging of specimens for transport to diagnostic laboratories for additional testing. Specimens should already be in a sealed, **decontaminated primary container**.
- Inactivated specimens (e.g., specimens in nucleic acid extraction buffer)
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Electron microscopic studies with glutaraldehyde-fixed grids

The following activities involving manipulation of potentially infected specimens should be performed in a Class II BSC:

- **Aliquoting and/or diluting specimens**
- **Inoculating bacterial or mycological culture media**
- Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
- Nucleic acid **extraction procedures** involving potentially infected specimens
- **Preparation and chemical- or heat-fixing of smears for microscopic analysis**

For additional detailed instructions please refer to the following:

Biosafety in Microbiological and Biomedical Laboratories (BMBL) – Fifth Edition

Laboratory Biosafety Manual – Third Edition

https://www.cdc.gov/coronavirus/2019-nCoV/index.html

https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

INFECTIOUS DISEASE TEST REQUEST FORM

UTAH PUBLIC HEALTH LABORATORY

4431 SOUTH 2700 WEST
TAYLORSVILLE, UTAH 84129
TELEPHONE: (801) 965-2400
FAX: (801) 536-0473
http://health.utah.gov/lab/infectious-diseases

FOR UPHL USE ONLY

LAB#

DATE STAMP

PLEASE PRINT CLEARLY AND FILL OUT AS COMPLETELY AS POSSIBLE.

PATIENT INFORMATION:

PATIENT STATE OF RESIDENCE	PATIENT COUNTY OF RESIDENCE	ZIP CODE	DATE OF BIRTH (mm/dd/yyyy)	AGE	SEX
			_____/_____/_____		M F
LAST NAME	**FIRST NAME**	Is Patient Insured? [ ] Yes [ ] No If Yes, will insurance be billed? [ ] Yes [ ] No		**STI TESTING ONLY:** Is patient MSM? [ ] Yes [ ] No	
PATIENT ID #	**ETHNICITY** [ ] Hispanic [ ] Non-Hispanic	**RACE** [ ] White [ ] Black or African American [ ] American Indian or Alaska Native [ ] Asian [ ] Native Hawaiian or other Pacific Islander			

PROVIDER INFORMATION
Provider Code:

Physician: _____
Provider Phone: _____
Provider Email: _____
Secure Fax #: _____

SPECIMEN COLLECTION DATE AND TIME

(mm/dd/yy) _____/_____/_____

Time: _____

SPECIMEN SOURCE/SITE (CHOOSE 1)**:**

[ ] Blood	[ ] (Endo)tracheal aspirate/wash	[ ] Plasma	[ ] Tissue (specify):_____
[ ] Body Fluid (specify):_____	[ ] Environmental (specify):_____	[ ] Rectum	[ ] Urethra
[ ] Bronchoalveolar lavage	[ ] Food (specify):_____	[ ] Serum	[ ] Urine
[ ] Bronchial aspirate/wash	[ ] Lesion (site):_____	[ ] Sputum (natural / induced)	[ ] Vagina
[ ] Cerebrospinal Fluid	[ ] Nasal (aspirate /swab / wash)	[ ] Stool	[ ] Wound/Abscess
[ ] Cervix	[ ] Nasopharyngeal swab	[ ] Throat swab	[ ] Other (specify): _____

BIOTERRORISM TESTS (Notify lab before submitting)

[ ] Isolate [ ] Original Material

[ ] Bacillus anthracis (Detection/ID)
[ ] Brucella species (Detection/ID)
[ ] Brucella antibody
[ ] Burkholderia mallei/pseudomallei (Detection/ID)
[ ] Clostridium botulinum culture & toxin
[ ] Coxiella burnetii (Detection)
[ ] Ebola virus (Detection)
[ ] Francisella tularensis (Detection/Identification)
[ ] F. tularensis antibody
[ ] MERS CoV
[ ] Orthopox viruses Detection
Virus Suspected:_____
[ ] Rickettsia (Detection)
[ ] Yersinia pestis (Detection/Identification)
[ ] Yersinia pestis antibody
[ ] Other (specify): _____

BACTERIOLOGY/TUBERCULOSIS TESTS

[ ] Isolate [ ] Original Material

[ ] Salmonella [ ] Shigella
[ ] E. coli O157 [ ] EHEC/STEC
[ ] Campylobacter [ ] Haemophilus Influenzae
[ ] Neisseria gonorrhea [ ] Neisseria meningitidis
[ ] OME Culture [ ] CRE/CRPA/CRAB
[ ] Vibrio/Plesiomonas/Aeromonas
[ ] Other (specify):_____

Tuberculosis Specimen
[ ] GeneXpert
[ ] Mycobacterial culture
Has patient received chest x-ray? [ ] Yes [ ] No
If YES, did patient show signs of cavitary disease?
[ ] Yes [ ] No
[ ] Mycobacterial referral
Presumptive ID:_____
[ ] Other (specify): _____

IMMUNOLOGY TESTS

[ ] QuantiFERON-TB Gold
REQUIRED information:
Blood draw date/time:_____
Incubation at 37°C completed? [ ] Yes [ ] No
Signature:_____
Incubation start date/time:_____
Incubation end date/time:_____

[ ] Syphilis IgG EIA (includes confirmatory testing)
[ ] Suspect acute infection/previous positive

[ ] HIV Antigen/Antibody (includes confirmatory testing)
[ ] Previous positive

[ ] Hepatitis C Antibody
[ ] HCV RNA Testing if Positive

[ ] Hepatitis B Antibody

[ ] Hepatitis B Antigen (includes confirmatory testing)

[ ] Hantavirus (Sin Nombre) IgG/IgM
[ ] Acute Serum (mm/dd/yy)_____/_____/_____
[ ] Convalescent serum (mm/dd/yy)_____/_____/_____

[ ] West Nile virus IgM (Human)

[ ] Zika virus IgM

ADDITIONAL INFORMATION

[ ] Other Disease Suspected: _____

[ ] Referral Test (additional form(s) **REQUIRED**)
***Contact UPHL for additional form(s)**

VIROLOGY TESTS

Aptima NAAT
[ ] C. trachomatis and N. gonorrhea by NAAT
[ ] Patient is partner of a 15-24 year old female

Virus Identification
[ ] Respiratory Panel (FilmArray)
[ ] Herpes Simplex/Varicella zoster PCR
(HSV-1, HSV-2, VZV)
[ ] Trioplex PCR (Zika, Dengue, Chikungunya Viruses)

Influenza PCR
[ ] Influenza A & B virus PCR (with subtyping/genotyping)

COMMENTS: